4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0077]

Draft Guidance for Industry on Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease." This guidance outlines FDA's current thinking as to how a sponsor could demonstrate efficacy in clinical trials in patients in the early stages of Alzheimer's disease that occur before the onset of overt dementia.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease." This guidance outlines FDA's current thinking as to how a sponsor could demonstrate efficacy in clinical trials in patients in the early stages of Alzheimer's disease (AD) that occur before the onset of overt dementia. Specifically, this guidance addresses FDA's current thinking regarding the selection of patients with early AD, or who are determined to be at risk of developing AD, for enrollment into clinical trials. The selection of outcome measures for trials in these populations that are designed to demonstrate a clinical benefit, as well as the manner in which disease modification

might be demonstrated, are also addressed. The design of clinical trials that are specifically focused on the treatment of patients with established Alzheimer's disease dementia (i.e., dementia of the Alzheimer's type), or any of the autosomal dominant forms of AD, are not explicitly discussed although many of the principles in this guidance will be pertinent.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing drugs for the treatment of early Alzheimer's disease. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: February 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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